How not to evaluate whether psychosocial interventions benefit patients

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Letter to the Editor

How not to evaluate whether psychosocial interventions benefit patients

Dear Editor,
Response to Salander.

We had trouble recognizing Fors *et al.*'s [1] systematic review from its depiction by Salander. Despite a thorough effort, Fors *et al.* identified only 18 randomized controlled trails (RCTs) evaluating psychosocial interventions for patients with non-metastatic breast cancer meeting minimal methodological standards and concluded that 'insufficient evidence exists to define optimal psychoeducational interventions beyond an information package that all cancer patients usually receive, [or]…to determine the most beneficial social and emotional support interventions, even though some subgroups with high initial cancer-related stress seem to benefit'. This stark evaluation was all the more impressive, given the tendency that we have noted [2,3] for some investigators to hide essentially null primary results with secondary and *post hoc* analyses so that interventions appear effective.

Salander identifies serious problems in the psycho-oncology literature, but undercuts his credibility with overstatement. Rather than 'few people with cancer desire psychological treatment' and 'there seems to be no relationship between psychological distress and desire for psychological treatment', a more accurate assessment is that *fewer cancer patients desire psychosocial intervention than is widely assumed* and that a *positive screening for distress is only a modestly efficient indicator of interest in psychosocial services* [4]. One implication of our assessment is that intervention trials assuming that most cancer patients want services will fail to meet accrual goals and could be compromised methodologically by efforts to accrue sufficient numbers of patients. Another implication is that reliance on screening positive for distress as a means of gatekeeping for access to services will likely deny services to patients who are motivated and who might get substantial benefits from services, even if they could not register a decrease in distress [4]. A final implication is that many cancer patients who volunteer for RCTs will not be sufficiently distressed to register a change in distress. Indeed, *post hoc* analyses of null results of a recent large trial of supportive expressive group therapy for early breast cancer patients showed that many of the groups did not have a single distressed participant [5]. Investigators designing an RCT for psychosocial services face the dilemma of choosing between entry criteria that yield patients representative of those who would seek services versus criteria likely to yield a sample capable of registering clinically significant decreases in distress. Moreover, given that many patients' distress is driven by unmet needs that do not fit the standard model of emotional distress but represent diverse issues such as pain, fatigue, and financial stress, we can ask whether distress is particularly useful as a unified construct to target for intervention.

Salander dramatizes stock criticisms of RCTs, but provides an alternative that is worse than RCTs for evaluating whether there is benefit to intervention. First, it is probably true that RCTs do not attract representative cancer patients, but offering free psychosocial treatment in an RCT may attract patients representative of those who would seek treatment if these interventions were offered under conditions of routine care.

Second, Salander's proposal to replace RCTs with quasi-experimental comparisons of patients who seek and receive psychosocial intervention versus those who did not want treatment would be doomed to yield very different groups of patients and so would not be readily interpretable. The infamous evaluation of the Bristol Cancer Help Centre (BCHC) adopted something similar to Salander's proposed design with disastrous effects [6]. BCHC staff were so confident of the benefits of their services and that patients preferred them that they deemed an RCT unethical. Instead, a non-randomized design was implemented comparing cancer patients choosing to attend the BCHC to those treated in conventional cancer treatment settings. Published results initially reported that BCHC patients had significantly worse survival than controls. Although this was most likely a result of sicker patients seeking treatments at BCHC, publicity generated by these results severely damaged the credibility of the BCHC and more generally set back the cause of psychosocial intervention in the UK.

We agree with some of Salander's points, but believe that important considerations are overlooked. For example, it seems unlikely that a substantial number of patients entered into RCTs are uninterested in services—such patients would

vote with their feet before or during the consent process. Yet we need to ask the sobering question of why we cannot give away psychosocial interventions in clinical trials, and we need to plan much more realistically for not being able to attract most patients to trials. Similarly, we believe there is a role for designs accommodating patient preference and focusing on generalizability without harming internal validity [7]. We do not, however, see Salander's model as such an improvement. It would not provide credible evidence of benefit to cancer patients or garner the support needed to ensure that psychosocial services are available and reimbursable.

References

1. Fors EA, Bertheussen GF, Thune I *et al*. Psychosocial interventions as part of breast cancer rehabilitation programs? Results from a systematic review. *Psycho-Oncology*. DOI: 10.1002/pon.1844.
2. Coyne JC, Lepore SJ, Palmer SC. Efficacy of psychosocial interventions in cancer care: evidence is weaker than it first looks. *Annals of Behavioral Medicine* 2006;**32**(2):104–110.
3. Stefanek ME, Palmer SC, Thombs BD, Coyne JC. Finding what is not there unwarranted claims of an effect of psychosocial intervention on recurrence and survival. *Cancer* 2009;**115**(24):5612–5616.
4. van Scheppingen C, Schroevers MJ, Smink A, van der Linden YM, Mul VE, Langendijk JA. Does screening for distress efficiently uncover meetable unmet needs in cancer patients?. *Psycho-Oncology* 2011, DOI: 10.1002/pon.1939.
5. Classen CC, Kraemer HC, Blasey C *et al*. Supportive–expressive group therapy for primary breast cancer patients: a randomized prospective multicenter trial. *Psycho-Oncology* 2008;**17**(5):438–447.
6. Bagenal FS, Easton DF, Harris E, Chilvers CED, McElwain TJ. Survival of patients with breast-cancer attending Bristol-Cancer-Help-Center. *Lancet* 1990; **336**(8715):606–610.
7. TenHave TR, Coyne J, Salzer M, Katz I. Research to improve the quality of care for depression: alternatives to the simple randomized clinical trial. *General Hospital Psychiatry* 2003;**25**(2):115–123.

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